

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D2090201	<b>(X3) Date Survey Completed</b>  11/08/2018
<b>Name of Provider or Supplier</b>  Sav Endoscopy, Pc	<b>Street Address, City, State</b>  4277 Richmond Ave, Staten Island, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of records and an interview with the laboratory director, the laboratory did not perform and document the quality control (QC) acceptability of the Hematoxylin and Eosin (H&amp;E) stain used for histopathology slides: Finding included; It was confirmed with the laboratory director on November 8, 2018, at approximately 11:15 AM that the laboratory failed to perform and document the QC acceptability of the H&amp;E stains from the date of the last survey of March 16, 2017, through the date of this survey. Approximately 3142 patient slides were tested and results reported for H&amp;E stains.</p>
<b>D6093</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on the lack of QC records and confirmed in an interview with the laboratory director on the day of the survey, the laboratory director failed to ensure that the QC</p>

program for histopathology was followed to assure quality laboratory services. Refer to D5473